Greater New York Hospital Association
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Kenneth E. Raske, President

April
Fourteen
2008

Carolyn Clancy, M.D.
Director
Agency for Healthcare Research and Quality
540 Gaither Road
Rockville, MD 20850

Via the Federal Rulemaking Portal

RE: AHRQ: RIN-0991-AA01- Patient Safety and Quality Improvement; Proposed Rule (Vol. 73, No. 29), February 12, 2008

Dear Dr. Clancy,

Greater New York Hospital Association (GNYHA) submits these comments in connection with AHRQ's proposed rule designed to implement the Patient Safety and Quality Improvement Act of 2005 (Act). GNYHA is a trade association that represents nearly 300 hospitals and continuing care facilities, all of which are not-for-profit, charitable organizations, or publicly sponsored organizations located in New York City, throughout New York State, as well as in New Jersey, Connecticut, and Rhode Island. GNYHA is committed to assisting its members as they strive to provide the highest quality health care to the patients they serve. In fact, our goal is to be a national leader among health care associations and a catalyst for change in the area of quality improvement and patient safety.

GNYHA believes that the Act can help the nation's health care institutions reduce the incidence of preventable medical errors by encouraging them to analyze and address the root causes of those errors and sharing the results of those analyses with other providers in a protected environment. The regulations that have been proposed to implement the Act provide opportunities to achieve this goal but may also pose unnecessary burdens on those that may desire to become a Patient Safety Organization (PSO) or to contract with a PSO.

Confidentiality

When does confidentiality attach?

GNYHA is concerned about the proposed timing for providers to report patient safety information to a PSO in order for the information to be considered protected "patient safety work product" (PSWP). As currently written in the regulations, certain materials that are being prepared for submission to the PSO may be deemed "unprotected." In the preamble to the proposed rule, the example given is a hospital that reviews a list of all near-misses reported within the past 30 days. If the purpose of the hospital's review is to analyze whether to report any or the entire list to the PSO, the analyses and deliberations are fully protected. However, the list itself is not protected unless it is actually reported.

GNYHA believes that the confidentiality protections should attach to this sensitive information earlier in the process when the information and materials for submission are being reviewed, assembled, and prepared for reporting. If the materials are deemed PSWP as they are being considered for submission and are therefore protected throughout the review and reporting process, it will allow for greater operational efficiencies as reports can be "batched" rather than submitted one at a time.

Copies vs. Originals:

The analysis in the preamble to the proposed rule with regard to differential treatment of "copies" versus "original" incident reports is, we believe, both confusing and creates an artificial distinction, particularly in this era of electronic submissions and given current approaches to record keeping. As noted in the preamble, a "copy" of an incident report if submitted to a PSO is considered protected PSWP; however, it seems that the "original" incident report documenting the same event is not protected. Health care organizations that are striving to improve the quality of the care they provide would be better served if all information that relates to a particular event that is reported to a PSO were deemed protected PSWP.

Conflict with State Law:

Under the proposed rule, it appears as though providers are not permitted to use patient safety information that is prepared for submission to the PSO for internal peer review or other quality assurance review purposes. This will require health care organizations that prepare materials for submission to the PSO and that are also required to comply with certain state mandated reporting regulations to create parallel processes within the organization in order to maintain the necessary confidentiality protections. For example, under New York's peer review and quality assurance confidentiality regulations the materials prepared for these purposes are protected only if used for the purposes intended by the statute. Therefore, assuming we are reading the proposed rule correctly, these protections can be lost if those materials are used for any other purpose. This may discourage health care organizations from submitting information to PSOs due to the costs associated with duplicative processes needed to comply with both state and federal

regulations. Notwithstanding these concerns, GNYHA understands the restrictions that both federal and state laws impose on peer review/quality improvement information that health care organizations seek to protect. Ultimately, GNYHA feels that the confidentiality should attach to the analysis and reporting of the occurrence of the adverse event rather than to the purpose for which the data are being used.

HIPAA Compliance

Business Associate Agreements:

GNYHA believes that the regulations should more clearly state that PSOs must be HIPAA-compliant. A provider that is a HIPAA covered entity must continue to comply with HIPAA by entering into a business associate agreement with the PSO that will be analyzing the health care provider's patient safety work product. However, the preamble to the regulations (see page 8128) states that providers and PSOs can choose their level of confidentiality and can choose whether to de-identify the information or not. This would not be sufficient under HIPAA and would put covered entities at risk of falling out of compliance.

The Definition of "Provider":

In the definitions section (see § 3.20, page 8173), the term "provider" is defined as an individual provider, hospital, and parent company. While this term is not only extremely broad and perhaps confusing in the sense that a hospital with a component PSO would technically be the provider twice over, the term "provider" as defined is also problematic in that it does not correlate with the definition of "health care provider" as used in HIPAA.

Component Organizations

GNYHA believes that the requirement that a hospital interested in becoming a PSO must build a completely separate infrastructure (from both technical and personnel perspectives) is unnecessarily restrictive and in turn costly – particularly for large health care systems where affiliated health care organizations operating within the same network could benefit from sharing quality data and the lessons learned from the review and analysis of adverse events. The proposed regulations should be clarified to specify that the firewall that a component PSO must create is intended not to block out the parent or affiliated hospitals but rather only those entities external to the affiliated organizations.

GNYHA believes that there is an advantage to health care systems becoming PSOs because the infrastructure for meaningful review and analysis of adverse and other events from a patient safety perspective already exists. Many of these affiliated institutions already interface from a quality assurance/performance improvement perspective but only to a limited degree, and are not able to benefit from shared case reviews because of the limitations of state confidentiality protections. Therefore, many of these multi-organizational systems would seek to become a PSO, solely for the purpose of performing system-wide quality assurance/performance improvement with the benefit

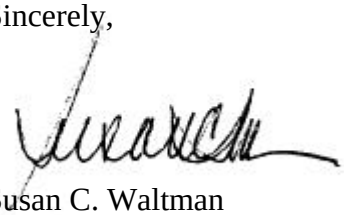
of the federal confidentiality protections afforded to certified PSOs. However, as currently constructed, the proposed regulations require the creation of a completely separate and resource intensive infrastructure resulting in an inefficient use of a health care system's limited resources.

Summary

The Patient Safety and Quality Improvement Act of 2005 and the proposed regulations provide health care organizations the opportunity to participate in quality improvement and patient safety activities in a more confidential environment. GNYHA has and will continue to work with its members to participate in activities that aim to effectively reduce the incidence of preventable medical errors.

GNYHA thanks AHRQ for the opportunity to comment on this proposed rule. Should you have any questions, please contact me, Lorraine Ryan at ryan@gnyha.org or (212) 506-5416 or Rebecca Urbach at rurbach@gnyha.org or (212) 258-5389.

Sincerely,



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